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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,563	06/30/2004	Pascale Laroche	0523-1015	5207

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YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,563

Applicant(s)

LAROCHE, PASCALE

Examiner

David J. Venci

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 1, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☒ Claim(s) 20-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 1, 2007, is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges Applicant's reply, filed October 1, 2007. Claims 20-38 are pending in this application. Claim 26-38 are direct to non-elected inventions and were withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b) in the Office Action, dated June 1, 2007.

Currently, claims 20-25 are under examination.

Claim Objections

Claim 24 references canceled claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by McHugh, *Flow Microsphere Immunoassay for the Quantitative and Simultaneous Detection of Multiple Soluble Analytes*, in *METHODS IN CELL BIOLOGY*, Vol. 42, 2d., Part B, Chapter 33, Darzynkiewicz, Z., Robinson, J.P., & Crissman, H.A. Eds., Academic Press, Inc. (1994).

McHugh describes a method for preparing an immunoreagent, the method comprising:

1. preparing categories of particles, each particle category associated with a different ligand (see paragraph bridging pp. 575-576, third sentence, "The different microsphere classes are coated with different capture reagents"), each particle category prepared by:
 - a. providing a range of particles varying by amount of associated ligand (see e.g., p. 581, Section B. **Passive Coating**, step 1, "The optimal concentration of protein must be determined experimentally"; see also, paragraph bridging pp. 588-589, third sentence, "coating conditions (capture reagent concentration)[...] can be altered") (paraphrasing mine), and determining across the range a curve of response signals across a known range of analyte concentrations (see paragraph bridging pp. 588-589, second sentence, "It is important to start with test samples which are known to lack the analyte of interest as well as test samples which contain the analyte of interest in varying concentrations");

- b. selecting a curve corresponding to the particles having:
 - i. the smallest amount of associated ligand giving a significant response signal that ensures reading precision over the known range of analyte concentrations (see paragraph bridging pp. 588-589, third sentence, "coating conditions (capture reagent concentration), incubation times and temperatures, and detection reagent concentration can be altered to maximize analytic sensitivity");
 - ii. compatibility with a sample dilution and labeling reagent (see paragraph bridging pp. 588-589, third sentence, "incubation times and temperatures, and detection reagent concentration can be altered to maximize analytic sensitivity");
- c. for the particles corresponding to the curve selected in step b), evaluating a mean signal (see e.g., paragraph bridging pp. 588-589, sixth sentence, "mean signal") associated with a point characteristic of the curve (see e.g., paragraph bridging pp. 588-589, sixth sentence, "cutoff");
- d. adjusting the mean signal evaluated in step c) by adjusting the amount of associated ligand (see paragraph bridging pp. 588-589, third sentence, "Once a clear differentiation between a negative and a strong positive is demonstrated then coating conditions (capture reagent concentration), incubation times and temperatures, and detection reagent concentration can be altered to maximize analytic sensitivity"), so that the mean signal for all categories of particles fall within a ratio of 1 to 5 (see e.g., Fig. 1, *noting* the fluorescence signals for the four particle categories are all within 4 decades of each other);

2. mixing all the categories of particles satisfying step 1(d) together in an appropriate solvent (see paragraph bridging pp. 576-577, "One the microsphere classes are coated with the appropriate capture reagent the different microsphere classes can be mixed").

With respect to claims 21 and 22, McHugh describes varying ligand concentration from 1 to 25 μg protein/ml during the coating step (see p. 581, Section B. **Passive Coating**, step 1).

With respect to claim 23, McHugh describes an example of using a common fluorescence scale for four different particle categories (see Fig. 1).

With respect to claim 24, McHugh describes the possibility of mixing all the particles together into one mixture (see paragraph bridging pp. 576-577, "One the microsphere classes are coated with the appropriate capture reagent the different microsphere classes can be mixed").

With respect to claim 25, McHugh describes various types of ligands, including antigens and antibodies (see paragraph bridging pp. 576-577, fourth sentence).

Response to Arguments

Specification

In prior Office Action, Examiner objected to the Specification for various reasons. Upon further principal consideration, and in view of Applicant's clarifying remarks and persuasive argumentation, these objections are withdrawn.

Claim Rejections - 35 USC § 112

In prior Office Action, claim 20 was rejected under 35 U.S.C. 112, second paragraph, because the phrases "homologous compound" and "the known measurement range of the analyte" lacked antecedent basis or were considered indefinite. Applicant's amendment and clarifying argumentation are persuasive and sufficient to overcome this rejection. Accordingly, this rejection is withdrawn.

Claim Rejections - 35 USC § 101

In prior Office Action, claims 20-25 were rejected under 35 U.S.C. 101 for allegedly lacking patentable utility. Upon further principal consideration, and in view of Applicant's clarifying remarks and persuasive argumentation, this rejection is withdrawn.

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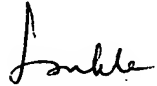
Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Assistant Examiner
Art Unit 1641

djv


LONG V. LE 12/21/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600